REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

A. Status of the Claims

Upon entry of this response, claims 1-3, 6-8, 12-17, and 53 will be pending. Claims 1 and 53 are amended presently. Exemplary support for the foregoing revisions exists in the specification, for example, in the paragraph bridging pages 9 and 10.

B. Specification – Reference to ISCOMATRIX™

The Examiner objected to the specification for allegedly using the trademark ISCOMATRIX™ in a manner that does not protect its proprietary nature or that includes "generic terminology." Applicants respectfully disagree.

Applicants have reviewed the entire specification and found that, in each occurrence, the term ISCOMATRIX™ is both capitalized and identified with the "™" designation. Additionally, the specification describes ISCOMATRIX™ in generic terms as an "immunostimulating complex of saponin, cholesterol and lipid." Moreover, page 12 of the specification, in the last paragraph, directs the knowledgeable reader to patent documents that describe the composition and preparation of ISCOMATRIX™.

The MANUAL OF PATENT EXAMINING PROCEDURE allows for the use of trademarks in patent applications, so long as the identity of the trademark is "clear" and the trademark has a "fixed and definite meaning." MPEP 608.01(v). This application complies with those requirements. Accordingly, Applicants request withdrawal of the rejection.

C. Reference to the Substitute Specification

The Examiner asked for clarification about when Applicants filed a substitute specification. Applicants filed a redlined copy of the patent specification on October 15, 2002 and a clean copy of the patent specification on December 12, 2002. Following those filings, Applicants submitted a certification that the substitute specification contains no new matter on August 25, 2003.

D. The Claims are Patentable over US 2004/0191270

Claims 1, 3, 6-8, 12-17 and 53 were rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by US 2004/0191270 ("Drane"). Applicants traverse the rejection.

Drane is not prior art. The earliest possible 102(e) date for Drane is November 19, 1999, the filing date of provisional application No. 60/166,652. The present application, however, has a priority date of February 17, 1999, based on Australian patent application No. PP8735/99 and a priority date of July 27, 1999, based on Australian patent application No. PQ1861/99. Both of these priority dates precede the earliest 102(e) date for Drane. Thus, Drane is not prior art, and the anticipation rejection should be withdrawn.

E. The Claims are Patentable over WO 96/33739

Claims 1, 3, 6, and 12-17 were rejected for alleged anticipation by WO 96/33739 ("Garcon"). The rejection acknowledged that Garcon does not *teach* an electrostatic association between an organic complex and an antigen, but takes an expansive view of the term "electrostatically associated" to include Garcon's entrapment of an antigen within an organic complex. To support that view, the rejection relies on a statement in the specification that "'electrostatically associated' is a reference to the organic carrier and the antigen being linked, bound or otherwise associated by means which include electrostatic interaction" (paragraph bridging pages 9-10).

Applicants disagree with the Examiner's interpretation of the specification. Nevertheless, the rejection is moot in view of the foregoing amendment to claim 1. As amended, claim 1 recites that the organic complex and antigen are "associated by an electrostatic interaction." Garcon neither teaches nor suggests such an interaction, and the specification draws a clear distinction between an electrostatic interaction and other forms of association, such as entrapment. Accordingly, the anticipation rejection should be withdrawn.

F. The Claims are Patentable over WO 96/33739

Claims 1, 3, 7, 12, 13, and 17 were rejected for alleged anticipation by WO 98/36772 ("MacFarlan"). Applicants traverse the rejection.

MacFarlan describes an immunostimulating complex matrix that comprises a saponin preparation, a sterol, a phospholipid, and a metal-chelating moiety capable of binding a polypeptide having at least one chelating amino acid sequence in the presence of metal ions. Thus, MacFarlan's invention relates to chelation.

Chelation involves the formation of a coordination complex characterized by bonding of a ligand to a central metal atom by coordinate covalent bonding. A coordinate covalent bond is a special covalent bond in which a donor atom supplies both electrons. (See, e.g., http://www.chem.purdue.edu/gchelp/cchem.whatis.html (copy printed 07/26/2006 attached)). Coordination complexes differ from complexes resulting from electrostatic interaction in at least two important ways: (i) heavy metal ions are essential to a coordination complex, but are neither required nor involved in electrostatic interactions, and (ii) the ligand and receptor in a coordination complex are joined by covalent bonds.

In MacFarlan's invention, therefore, the metal ions (*e.g.*, Ni^{2+}) are electrostatically bound to the chelating moiety (*e.g.*, iminodiacetic acid (IDA)), which fully neutralizes the charge on the metal ions but leaves coordination sites available on the metal for electron sharing to occur. As such, MacFarlan's immunostimulating complex matrix is uncharged. Also, the amino acids involved in chelation most commonly are histidine and cysteine, but neither of these amino acids is charged in the pH range at which polypeptides normally are purified. See, e.g., USP 5,169,936, USP 4,569,794 & USP 4,877,830. Because MacFarlan's immunostimulating complex matrix and polypeptides are uncharged, they do not associate by electrostatic interaction.

Without an electrostatic interaction between MacFarlan's immunostimulating complex matrix and polypeptides, MacFarlan does not anticipate the claimed invention. Withdrawal of the rejection is appropriate, therefore.

G. The Claims are Patentable over the combination of MacFarlan and Garcon

Claims 6, 8, and 53 were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over MacFarlan in view of Garcon. According to the rejection, one of ordinary

skill in the art would have used the teaching of Garcon to modify the charge on MacFarlan's complex. Applicants traverse the rejection.

As explained in previous sections of this response, neither MacFarlan nor Garcon teaches or suggests an organic complex and antigen "associated by an electrostatic interaction." Thus, neither reference remedies this deficiency in the other. Withdrawal of the obviousness rejection is therefore appropriate.

H. Double Patenting

Claims 1, 3, 6-8, 12-17 and 53 remain provisionally rejected on grounds of obviousness-type double patenting over claims of copending U.S. patent application No. 10/622,470. Because the rejection is still provisional, Applicants continue to defer any argument or "corrective" action concerning the rejection until the Office allows claims in one of the copending applications.

CONCLUSION

This application is in condition for allowance, Applicants believe, and they therefore request favorable reconsideration of the application. If the Examiner believes that an interview would advance prosecution, she is invited to contact the undersigned.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card authorization being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extensions under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

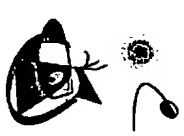
Respectfully submitted,

Date 27 July 2006

By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768



What Is A Coordination Compound?

A ***coordination complex*** is the product of a Lewis acid-base reaction in which neutral molecules or anions (called ***ligands***) bond to a central metal atom (or ion) by ***coordinate covalent bonds***.

- Ligands are Lewis bases - they contain at least one pair of electrons to donate to a metal atom/ion. Ligands are also called ***complexing agents***.
- Metal atoms/ions are Lewis acids - they can accept pairs of electrons from Lewis bases.
- Within a ligand, the atom that is directly bonded to the metal atom/ion is called the ***donor atom***.
- A coordinate covalent bond is a covalent bond in which one atom (i.e., the donor atom) supplies both electrons. This type of bonding is different from a normal covalent bond in which each atom supplies one electron.
- If the coordination complex carries a net charge, the complex is called a ***complex ion***.
- Compounds that contain a coordination complex are called ***coordination compounds***.

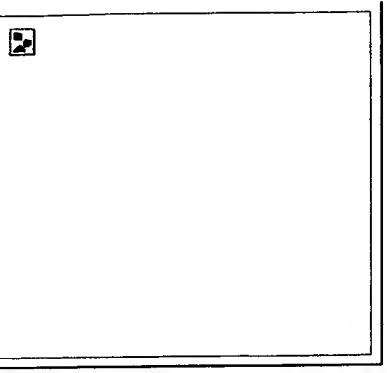
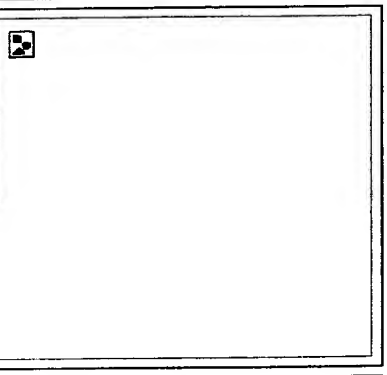
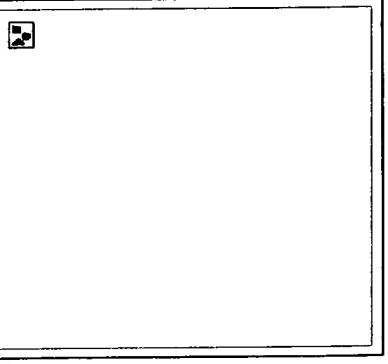
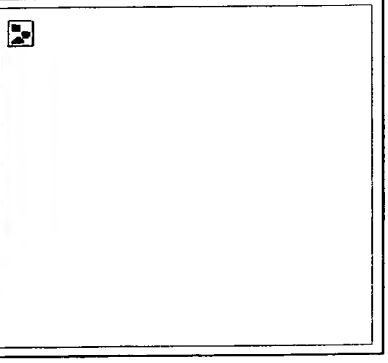
Coordination compounds and complexes are distinct chemical species - their properties and behavior are different from the metal atom/ion and ligands from which they are composed.

The ***coordination sphere*** of a coordination compound or complex consists of the central metal atom/ion plus its attached ligands. The coordination sphere is usually enclosed in brackets when written in a formula.

The ***coordination number*** is the number of donor atoms bonded to the central metal atom/ion.

Some Coordination Complexes

example	molecular formula	Lewis base/ligand	Lewis acid	donor atom	coordination number
	$[Ag(NH_3)_2]^+$	NH_3	Ag^+	N	2

	$[Zn(CN)_4]^{2-}$	CN^-	Zn^{2+}	C	4
	$[Ni(CN)_4]^{2-}$	CN^-	Ni^{2+}	C	4
	$[PtCl_6]^{2-}$	Cl^-	Pt^{4+}	Cl	6
	$[Ni(NH_3)_6]^{2+}$	NH_3	Ni^{2+}	N	6